

8EHQ-0295-13330
4EHQ-95-13330

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PUBLIC NOTICE COPY

February 6, 1995

A

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
P 253 155 587

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RECEIVED

OPPT Document Processing Center (7407)
ATTN: Section 8(e) Coordinator
Office of Pollution Prevention and Toxics (OPPT)
US Environmental Protection Agency
Washington, DC 20460

RE: TSCA Section 8(e) Notice

COMPANY SANITIZED

Dear Sir or Madam:

This notice is being submitted by Rhône-Poulenc Ag Company (RPAC) to the Environmental Protection Agency (EPA) in accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), 15 USC § 2607 (e).

We are submitting the results of toxicity studies on

Only limited quantities of this compound have been synthesized for research and development purposes.

RPAC claims the alpha-numeric designation and the specific chemical identity of the substance at issue to be confidential business information (CBI). The chemical substance may be nonconfidentially identified as a "heterocycle".

In a Chernoff-Kavlock assay, pregnant CD-1 mice (20 females/group) were dosed by gavage on gestation days 6 through 13, inclusive. Mice were allowed to litter naturally, and pup viability and growth was observed on postnatal days 1 through 4. For at 100 mg/kg/day, 17 of 20 females died during the study. One additional female had complete litter resorption, and the two remaining females had viable litters. No evidence of toxicity was noted in the pups from these litters. AT 25 mg/kg/day, no maternal toxicity was observed, but a statistically significant decrease in the mean number of viable male pups per litter was noted on postnatal days 1 and 4 (5.6 compared to a control of 7.4 on postnatal day 1 and 5.4 compared to a control of 7.1 on postnatal day 4). However, no effects were noted on the mean number of female pups per litter or on the mean number of pups per litter for males and females combined. Percent prenatal loss at 25 mg/kg/day was statistically higher than control (21.1% compared to a control of 9.3%). Pup weight for females was statistically lower than control on postnatal day 1, but weights for both male and female pups were statistically higher than control on postnatal day 4.

In a subchronic toxicity study, test material was administered to male CD-1 mice via admixture in the diet at levels of 30 or 100 ppm (10 mice/group) for 8 weeks. Mortality was 20% at 30

mm
2/28/95

ppm and 100% at 100 ppm. Clinical signs of reduced motor activity, irritability to touch, piloerection, and hunched posture were observed at both 30 and 100 ppm. Necropsy of animals that died during the study revealed red fluid, possibly blood, in abdominal and thoracic cavities of some of the animals at 100 ppm. Extramedullary hemopoiesis in the spleen and centrilobular and hemorrhagic necrosis in the liver were observed in a few animals at 100 ppm. Animals at 30 ppm surviving to study termination exhibited changes in the liver consisting of periportal fatty change and centrilobular hypertrophy.

SUPPORT INFORMATION OF CONFIDENTIALITY CLAIMS

1. Claims of confidentiality are being made on behalf of RPAC.
2. RPAC asserts this claim of confidentiality until such time as a specific chemical is approved for use in the United States. In the event that the chemical is never approved, RPAC asserts that the CBI information should be provided permanent protection. The structure and use of the chemical are unique. Disclosure of this information would provide our competitors with information on facets of our business that would be detrimental to our competitive position.
3. The information claimed as confidential has not been previously disclosed to any other governmental agency or to EPA.
4. This information has been disclosed to only a very limited number of investigators outside of RPAC who have performed either toxicity or efficacy testing. These individuals operate under a strict secrecy agreement. Any individuals who may work with the chemical will have all health/toxicology information disclosed to them as well, but only on the basis of strict secrecy and respect for the CBI nature of the information.
5. Any individuals to whom the CBI is revealed are warned of the nature of the information. Further, they are informed of their obligations to maintain secrecy should they terminate their employment with RPAC.
6. None of the information claimed as confidential appears in or is referred to in any advertising or promotional materials for the chemical or the end product containing it, professional or trade publications, or any other media available to the public or to our competitors. Appropriate warnings do appear on safety data sheets, as RPAC considers that individuals who are requested to work with the chemicals have every right to know as much about the chemicals' toxicity as possible. Further, the information is only considered to be CBI with respect to the general public, insofar as our competitors could use the information in an unfairly competitive nature.
7. No previous confidentiality determinations have been made by EPA, other Federal agencies or courts in connection with this information.
8. RPAC believes that disclosure of this information to the general public would be likely to result in substantial harm to its competitive position. Disclosure of the **alpha numeric designation** and **chemical name** would provide some competitors with information about the specific chemistry of this area of our research and our business. Further, the type of toxicological testing being reported in the TSCA 8(e) notice would provide competitive information about this chemical's status in the research and development process and, therefore, the time remaining until commercialization.
9. A patent has not been issued for the specific chemical structure. However, the generic chemical structure is covered by a patent that is currently pending.

10. The chemical is not available commercially. It is in the earliest stages of research and development for pesticide use and is unlikely to be developed into a commercial product.

11. We believe that disclosure of the chemical name would allow a competitor to synthesize this chemical. RPAC has invested a large amount of time and money into research of this particular chemical family, and information on specific chemical structures would harm our competitive position.

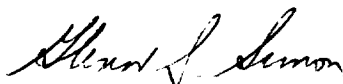
12. Disclosure of the chemical structure might reveal information on processes used to synthesize this compound.

13. CAS number has not yet been assigned.

14. Currently, the chemical is not the subject of FIFRA regulation or reporting.

Further questions regarding this submission may be directed to the undersigned at 919-549-2222.

Sincerely,



Glenn S. Simon, PhD, DABT
Director of Toxicology



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Glenn S. Simon, Ph.D., DABT
Director of Toxicology
Rhône-Poulenc
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 18 1995

EPA acknowledges the receipt of information submitted by your organization under Section (e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

13330A



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contains at least 50% recycled fiber

Triage of 8(e) Submissions

Date sent to triage: APR 19 1995

NON-CAP

CAP

Submission number: 13330A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.):

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document:

1

2

pages

1, 2, 3

pages

1, 2, 3

Notes:

Contractor reviewer :

PAR

Date:

4/3/95

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # 8EHQ-0295-133303 Seq. A

TYPE INT. SUPP FLWP

SUBMITTER NAME: Rhoads - Poulenc
Ag Company

INFORMATION REQUESTED: FLWP DATE
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
REFER TO CHEMICAL SCREENING
W/ CAP NOTICE

SUB. DATE: 02/06/95 OTS DATE: 02/13/95 CSRAD DATE: 02/28/95

CHEMICAL NAME: Heterocycle
CONFIDENT

- ADJUTANT ACTIONS:
0401 NO ACTION REPORTED
0402 STUDIES PLANNED IN WORK
0403 NOTIFICATION OF WORKING CONDITIONS
0404 LABEL/MSDS CHANGES
0405 PROCESS/ANDI INC. CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPICLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCUR/REL FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQUEST DELAY	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/COMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0259 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0229 METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0230 METAB/PHARMACO (HUMAN)	01 02 04		

USE: R-D pesticide

TOXICOLOGICAL CONCERN:

SPECIES: Mice

ONGOING REVIEW: YES (DROP/REFER) NO (CONTINUE)

NON-CBI INVENTORY: YES NO

CAS SR: Non - CBI

screening assay: 100 mg/kg - 17% died
85 mg/kg - pregnant mice increased, saw out of female pups on day 1

CECATS DATA: 0895-133303 SEQ. A
Submission # SEHO: 0895-133303 SEQ. A

TYPE INT SUPP FLWP

SUBMITTER NAME: Phase - Poulsen

Ag Company

SUB DATE: 02/06/95 OTS DATE: 03/13/95 CSRAD DATE: 02/26/95

CHEMICAL NAME:

Hexocycle

CASE

Confident

INFORMATION REQUESTED: FLWP DATE:
6001 NO INFO REQUESTED
6002 INFO REQUESTED (TEC1)
6003 INFO REQUESTED (VOL ACTIONS)
6004 INFO REQUESTED (REPORTING RATIONAL/FI)
6005 INFO REQUESTED (REPORTING RATIONAL/FI)
6006 INFO REQUESTED (REPORTING RATIONAL/FI)
6007 INFO REQUESTED (REPORTING RATIONAL/FI)
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ADDITIONAL ACTIONS:
6001 NO ACTION REQUIRED
6002 ACTION REQUIRED (TEC1)
6003 ACTION REQUIRED (VOL ACTIONS)
6004 ACTION REQUIRED (REPORTING RATIONAL/FI)
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6100 ACTION REQUIRED (REPORTING RATIONAL/FI)

INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.
0201 ONCO (HUMAN)	01 02 04	0216 EFFICACY	01 02 04	0211 BAKING (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0212 BAKING (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0213 CHEMISTS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0214 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 BIOLOGICAL TOX	01 02 04	0215 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCURRENCE/FATE	01 02 04	0216 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 ENV. EXPOS OF ENV CONTAM	01 02 04	0217 DNA DAMAGE/PAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSES REPORT DELAY	01 02 04	0218 PRODUSE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PRODUSE/PROC ID	01 02 04	0219 MAIDS	01 02 04
0210 ACUTE TOX (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0220 OTHER	01 02 04
0211 CHR. TOX (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
0212 ACUTE TOX (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0229 METABOLISM (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0230 METABOLISM (HUMAN)	01 02 04		

INFORMATION: NON-CL INVENTORY ONGOING REVIEW STAGES TOXICOLOGICAL CONCERN USE PRODUCTION

CAS SR NO YES YES (OR REFER) NO (CONTINUE)

(IN FLUORENCE)

HIGH

PID pesticide

UNRECORDED NON - GOF Mice fed "hexocycle" compound in the diet at levels of 300 or 100 ppm for 8 weeks. Mortality was 20% at 30 ppm and 100% at 100 ppm. Clinical signs of reduced motor activity, inability to touch, piloerection were observed at both 30 and 100 ppm. Necropsy of animals that died during the study revealed red fluid, possible blood, in abdominal and thoracic cavities at the beginning. Enlarged kidneys were observed in the spleen, central lobular and hemorrhagic necrosis in the liver. Animals at 30 ppm surviving to study for necropsy exhibited changes in the liver consisting of peripheral fatty changes and central lobular hyperplasia.